



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/911,277	07/23/2001	Frank-Gerhard Boss	Le A 34 494	4089

7590

09/08/2003

Jeffrey M. Greenman
Vice President, Patents and Licensing
Bayer Corporation
400 Morgan Lane
West Haven, CT 06516

EXAMINER

HUI, SAN-MING R

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 09/08/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/911,277

Applicant(s)

BOSS ET AL.

Examiner

San-ming Hui

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____. |

Art Unit: 1617

DETAILED ACTION

Applicant's amendments filed June 18, 2003 have been entered.

The addition of claims 10-16 in the amendments filed June 18, 2003 is acknowledged.

The outstanding rejection under 35 USC 112, second paragraph is withdrawn in view of the amendments filed June 18, 2003.

The outstanding rejection under 35 USC 102 is withdrawn in view of the amendments filed June 18, 2003.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the selective PDE2 inhibitors of formula (I), does not reasonably provide enablement for other suitable selective PDE2 inhibitors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In the instant case, the specification fails to disclose the structural limitations of PDE 2 inhibitors. Only the functional limitations "compounds that inhibit PDE 2, which inhibits human PDE2 more strongly than it inhibits the human cAMP PDEs 3B, 4B, and

Art Unit: 1617

7B", and "compounds with IC₅₀ less than 10 μ M" are disclosed. It is obvious that, from the term "selective PDE 2 inhibitor", these compounds will inhibit PDE 2 selectively. However, the specification fails to provide any structural information or characteristics, other than the compounds of Formula (I), for one of skilled artisan to ascertain what these compounds may be useful for the instant invention. How many compounds, other than the ones in formula (I), are encompassed by the claims? Applicant has not specifically defined any of the PDE 2 inhibitors that fall within the broad genus claimed (Please note the claims herein read on all PDE 2 inhibitors, which includes compounds that are not represented by formula (I)) nor does Applicants describe any structural characteristics commonly possessed by all PDE 2 inhibitors such that one of skill in the art would recognize that would require undue experimentation to ascertain these compounds. Absent showing such information, the specification does not provide adequate support for the full breadth of the claims herein. In regards to the functional language recited herein, attention is directed to *General Electric Company v. Wabash Appliance Corporation et al* 37 USPQ 466 (US 1938), at 469, speaking to functional language at the point of novelty as herein employed: "the vice of a functional claim exists not only when a claim is "wholly" functional, if that is ever true, but when the inventor is painstaking when he recites what has already been seen, and then uses conveniently functional language at the exact point of novelty". Functional language at the point of novelty, as herein employed by Applicants, is further admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC 1997) at 1406: stating this usage does "little more than outlin[e] goals appellants hope the recited

Art Unit: 1617

invention achieves and the problems the invention will hopefully ameliorate”.

Applicants functional language at the point of novelty fails to meet the requirements set forth under 35 USC 112, first paragraph. Claims employing functional language at the point of novelty, such as Applicants', neither provide those elements required to practice the inventions, nor “inform the public during the life of the patent of the limits of the monopoly asserted” *General Electric Company v. Wabash Appliance Corporation et supra*, at 468. Claims thus constructed provide no guidance as to medicaments employed, levels for providing therapeutic benefit, or provide notice for those practicing in the art, limits of protection. Simply stated, the presented claims are an invitation to experiment, not reciting a specific medicament regimen useful for practicing the instant invention.

Response to Arguments

Applicant's arguments in regards to the newly added limitation in claim 1 have been considered, but are not found persuasive. As discussed above, the recitation of functional language simply is an invitation of experiment because it describes what the compounds can do but not what they are.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 3-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haning et al. (WO 98/40384), the equivalent of this patent is USPN 6,174,884 B1, in view of Whalin et al. and Egawa et al.. All references herein are made to the English language patent, reference of the record.

Haning et al. teaches a method of treating cerebrovascular diseases (e.g., stroke) comprising administering to a patient the herein claimed PDE-II inhibitory compound of formula I, including the compound represented by example 39 (which

Art Unit: 1617

reads on formula (I) compound of claim 9 in the instant application), see col. 43, lines 25-45, see also col. 13 line 50 to col. 14 line 61.

Haning et al. does not expressly teach the particular manifestations/symptoms of a stroke (e.g., impaired memory, perception, learning ability). Haning et al. does not expressly teach the method of treating impaired memory, perception, or learning ability caused by other disorders recited herein.

Whalin teaches HL-725, also known as trequinsin, a potent inhibitor of isolated PDE II activity in vitro can cause 1) increased basal cAMP accumulation, 2) potentiation of adenosine-stimulated cAMP accumulation, and 3) retardation of the rate of cAMP decay (See particularly abstract).

Egawa et al suggests the therapeutic effects of a PDE IV inhibitor, rolipram, for learning and memory impairment is result from the indirect potentiation of various transmitters by an increase in cAMP through the inhibition of PED4 (See particularly the abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the method of Haning in treating disorders of perception, learning, concentration or memory regardless of the causative conditions may be.

One of ordinary skill in the art would have been motivated to employ the method of Haning in treating disorders of perception, learning, concentration or memory resulted from stroke because disorders of perception, learning, concentration or memory are known to result from a stroke. Treating the underlying cause of these disorders would

Art Unit: 1617

therefore be reasonably expected to effectively treat these symptomatic/secondary disorders, absent evidence to the contrary.

One of ordinary skill in the art would have been motivated to employ the method of Haning in treating disorders of perception, learning, concentration or memory resulted from other conditions recited herein. It is known that increase the cAMP resulting amelioration of memory/learning impairment. Therefore, one of ordinary skill in the art would be reasonably expect to employ any known potentiator of cAMP and enhancer for cAMP accumulation, including the present compounds, to be similarly effective in relieving memory and learning impairment regardless of the causative conditions may be.

Response to Arguments

Applicant's arguments filed June 18, 2003 averring the cited prior art's failure to teach the instant compounds as selective PDE2 inhibitors have been fully considered but they are not persuasive. The cited prior art teaches compounds such as the one exemplified in example 39 of Haning, which reads on to the herein claimed compounds, as useful in treating cerebrovascular diseases (e.g., stroke). Since the compound of example 39 in Haning is one of the compounds of formula (I) recited in the claims, it must have the herein claimed PDE2 selectivity.

Applicant's arguments with respect to rejection over Whalin in view of Egawa have been considered but are moot in view of the new ground(s) of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Application/Control Number: 09/911,277
Art Unit: 1617

Page 9

San-ming Hui
Patent Examiner



SREENI PADMANABHAN
PRIMARY EXAMINER

9/8/03